

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Opara  
Serial No. To Be Assigned  
Filed: Concurrently Herewith  
For: METHODS OF ENCAPSULATING CELLS

January 23, 2002

BOX PATENT APPLICATION  
Commissioner for Patents  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

Sir:

Please enter the following Preliminary Amendment before examining the pending application.

IN THE SPECIFICATION:

At page 1, line 2, after "Related Applications" please substitute the following paragraph.

--This application is a divisional of U.S. Application Serial No. 09/453,348 filed December 1, 1999, which is a continuation-in-part of commonly owned, copending application Serial No. 09/273,407, filed March 22, 1999, the disclosures of which are incorporated by reference herein in their entirety. --

IN THE CLAIMS:

Please cancel Claims 1-5, 14-76 and 78-83, without prejudice thereto.

**Please enter the following amended claims:**

6 (amended). A product according to claim 77, where said microcapsule comprises a polysaccharide gum surrounded by a semipermeable membrane.

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7 (amended). A product according to claim 77, where said microcapsule comprises alginate in combination with polylysine, polyornithine, and combinations thereof.

8 (amended). A product according to claim 77, wherein said microcapsule has an internal cell-containing core of alginate.

9 (amended). A product according to claim 8 wherein said internal cell-containing core of alginate is gelled.

10 (amended). A product according to claim 77, wherein said internal cell-containing core of alginate is not gelled.

11 (amended). A product according to claim 77, wherein said microcapsule has a diameter of from about 50  $\mu\text{m}$  to about 2 mm.

12 (amended). A product according to claim 77, wherein said microcapsule has a diameter of from about 200  $\mu\text{m}$  to about 1000  $\mu\text{m}$ .

13 (amended). A product according to claim 77, wherein said microcapsule has a diameter of from about 300  $\mu\text{m}$  to about 700  $\mu\text{m}$ .

77 (amended). A microencapsulated islet cell product comprising microcapsules containing isolated living pancreatic islet cells therein, said microencapsulated islet cells exhibiting a weight gain of not more than 10 percent by weight over a period of one month in physiological saline solution at 37 degrees Celsius and exhibiting at least 150 percent basal insulin secretion in response to 16.7 milliMolar glucose challenge in Krebs-Ringer physiological solution at pH 7.4 after said period of one month.

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**Please add the following new claim:**

84 (new). A microencapsulated islet cell product comprising microcapsules containing isolated living pancreatic islet cells therein, said microencapsulated islet cells exhibiting a weight gain of not more than 10 percent by weight over a period of one month in physiological saline solution at 37 degrees Celsius and exhibiting at least 150 percent basal insulin secretion in response to 16.7 millimolar glucose challenge in Krebs-Ringer physiological solution at pH 7.4 after said period of one month;

wherein said microcapsule comprises a polysaccharide gum surrounded by a semipermeable membrane;

and wherein said microcapsule has a diameter of from about 300  $\mu\text{m}$  to about 700  $\mu\text{m}$ .

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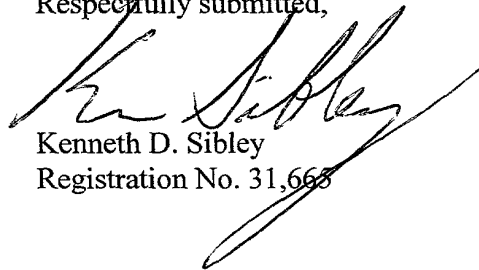
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### Remarks

The changes made to the claims above are shown in the attached "version with markings to show changes made".

It is respectfully submitted that this application is in condition for substantive examination, which action is respectfully requested.

Respectfully submitted,



Kenneth D. Sibley  
Registration No. 31,663



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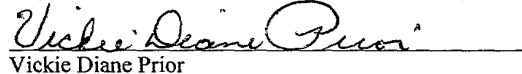
PATENT TRADEMARK OFFICE

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Vickie Diane Prior

Date of Signature: January 23, 2002

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**Version with Markings to Show Changes Made**

6 (amended). A product [method] according to claim [1] 77, where said microcapsule comprises a polysaccharide gum surrounded by a semipermeable membrane.

7 (amended). A product [method] according to claim [1] 77, where said microcapsule comprises alginate in combination with polylysine, polyornithine, and combinations thereof.

8 (amended). A product [method] according to claim [1] 77, wherein said microcapsule has an internal cell-containing core of alginate.

9 (amended). A product [method] according to claim 8 wherein said internal cell-containing core of alginate is gelled.

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11 (amended). A product [method] according to claim [1] 77, wherein said microcapsule has a diameter of from about 50  $\mu\text{m}$  to about 2 mm.

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physiological saline solution at 37 degrees Celsius [(exhibiting the durability thereof)] and exhibiting at least 150 percent basal insulin secretion in response to 16.7 milliMolar glucose challenge in Krebs-Ringer physiological solution at pH 7.4 after said period of one month.

84 (new). A microencapsulated islet cell product comprising microcapsules containing isolated living pancreatic islet cells therein, said microencapsulated islet cells exhibiting a weight gain of not more than 10 percent by weight over a period of one month in physiological saline solution at 37 degrees Celsius and exhibiting at least 150 percent basal insulin secretion in response to 16.7 milliMolar glucose challenge in Krebs-Ringer physiological solution at pH 7.4 after said period of one month;

wherein said microcapsule comprises a polysaccharide gum surrounded by a semipermeable membrane;

and wherein said microcapsule has a diameter of from about 300  $\mu\text{m}$  to about 700  $\mu\text{m}$ .

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